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Brief Report

Door openings in the operating room are associated with increased environmental contamination

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Door openings in the operating room (OR) have been hypothesized to increase OR environmental contamination. This study measured average colony-forming units (CFU) in the OR as a function of door openings and other potentially important variables. Bacterial settle plates were placed inside and outside of laminar airflow (LAF) by both exit doors, on the instrument table, and on the back instrument table (if applicable) for 48 orthopedic and general surgery procedures. CFU data were paired to *Staphylococcus aureus* colonization status, door openings, surgery duration, time of day, OR location, number of staff, use of warming devices, temperature, and humidity. The number of door openings in the OR and surgery duration were significantly associated with increased CFU in the OR overall and outside of LAF. However, under LAF conditions, only the number of OR personnel was significantly associated with increased CFU.

Surgical site infections (SSIs) dramatically increase length of hospital stay, hospital costs, and patient morbidity after surgery.[1] Most SSIs originate from endogenous patient flora and are presumed to be a result of inoculation of the operative site at the time of the surgery.[2,3] In a minority of cases, contamination of the operating room (OR) environment has been documented as an important source of SSI, often only identified in the setting of a cluster or outbreak.[4]

Laminar airflow (LAF) has been shown to decrease bacterial colony-forming units (CFU) around the operating field[5,6] and is used by some institutions to prevent SSIs, although the benefit of LAF is controversial.[7] Mixed results regarding the benefits of LAF may result from compromised function of the airflow system in the setting of excessive door openings and OR traffic.[5,8,9] In a study of exclusively orthopedic procedures, the number of door openings per case ranged from 0 to 66, with an average of 17.4 door openings per case.[6] A different orthopedic group reported an average of 60 door openings per case (0.64 door openings per minute) for primary arthroplasty procedures, and an average of 135 door openings per case in revision arthroplasty (0.84 door openings per minute).[10] In this study, we measured environmental contamination in the OR as a function of door openings, LAF, and other variables.

METHODOLOGY

Bacterial settle plates (Remel; Lenexa, Kansas) were placed inside and outside of LAF by exit doors, on the instrument table, and on the back instrument table (if applicable) for 48 orthopedic and general surgery procedures over a 6-week period. Different plates were used for the period of time from surgical kit opening until incision and from incision to closure. CFU were counted on each plate by trained microbiologists who were blinded to all other aspects of the study, and average CFU per plate were measured. The patient's *Staphylococcus aureus* colonization status, surgery duration, time of day, OR location, number of staff, use of Bair Hugger warming devices, temperature, and humidity were measured for each case from hospital databases. Number of door openings was manually counted by research personnel. In all cases, OR personnel were not blinded to participation in the study and were aware that door openings were being counted during these surgical cases. All ORs use a vertical LAF system (BioAir Systems; Greensboro, North Carolina), which uses a combination of outside and return air through HEPA filters. The HEPA filters are replaced every 3 years. These LAF units are connected to a heating, ventilation, and air conditioning (HVAC) system that is dedicated to the hospital's ORs. This HVAC system has pre-filters that are replaced quarterly and final filters that are

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Table 1
Average colony-forming units (CFU) for studied variables

Variable	Total		Outside LAF		Inside LAF	
	Mean CFU (range)	*P*-value	Mean CFU (range)	*P*-value	Mean CFU (range)	*P*-value
Time of day						
Morning	2.63 (0.00 – 13.6)	.45	3.81 (0.00 – 15.0)	.41	0.98 (0.00 – 12.0)	.52
Afternoon	1.69 (0.33 – 4.38)		2.56 (0.00 – 7.00)		0.75 (0.00 – 1.50)	
Operating room location						
New pod	3.45 (0.75 – 8.6)	.24	5.50 (1.50 – 15.0)	.30	0.81 (0.00 – 2.50)	.73
Old pod	2.28 (0.00 -13.6)		3.23 (0.00 – 9.50)		0.96 (0.00 – 12.0)	
Number of staff*						
5-6	1.35 (0.00 – 4.33)	.09	1.80 (0.00 – 5.50)	.35	0.50 (0.00 – 2.00)	*.03*
7-8	2.17 (0.25 – 8.57)		3.52 (0.00 – 15.0)		0.60 (0.00 – 2.50)	
9-10	2.19 (0.25 – 5.13)		3.96 (0.50 – 9.00)		0.96 (0.00 – 2.50)	
11-12	4.26 (0.50 – 13.3)		4.67 (1.00 – 9.00)		2.58 (0.00 – 12.0)	
Time frame†						
Case setup	-		-		0.54 (0.00 – 2.50)	*.02*
Surgery	-		-		0.41 (0.00 – 9.50)	
Duration*						
<140 min	2.13 (0.00 – 13.3)	.09	2.60 (0.00 – 9.00)	*.0016*	1.06 (0.00 – 12.0)	.92
>140 min	2.82 (0.50 – 5.75)		4.60 (1.00 – 15.0)		0.81 (0.00 – 2.50)	
Door openings*						
20-39	1.52 (0.00 – 4.38)	*.03*	2.20 (0.00 – 7.00)	*.0012*	0.50 (0.00 – 2.00)	.73
40-59	2.62 (0.25 – 13.3)		3.26 (0.50 – 9.50)		1.27 (0.00 – 12.0)	
60-79	2.86 (0.50 – 8.57)		4.78 (1.00 – 15.0)		0.39 (0.00 – 2.00)	
80 +	3.65 (0.88 – 5.88)		5.93 (1.50 – 9.50)		1.29 (0.50 – 2.50)	
Door openings/min*						
0.20-0.29	1.85 (0.00 – 4.38)	.15	2.85 (0.00 – 7.00)	.31	0.65 (0.00 – 2.50)	.20
0.30-0.39	1.95 (0.25 – 5.75)		3.05 (0.00 – 9.50)		0.66 (0.00 – 2.00)	
0.40-0.49	3.29 (0.33 – 8.57)		5.08 (0.00 – 15.0)		0.92 (0.00 – 2.50)	
≥ 0.50	3.38 (0.50 – 13.3)		3.64 (1.00 – 9.00)		2.14 (0.00 – 12.0)	
Colonization status						
MSSA‡	2.13 (1.50 – 3.25)	.70	4.60 (3.00 – 6.50)	.86	0.80 (0.00 – 2.50)	.78
No MSSA	1.88 (0.25 – 3.67)		4.44 (0.00 – 9.50)		0.94 (0.00 – 2.50)	

All analyses used the 2-sided Wilcoxon 2-sample test unless otherwise specified. *CFU*, colony-forming units; *LAF*, laminar airflow.
*Analysis by univariate linear regression.
†Differentiation between case setup and surgery was only performed for plates inside LAF; operating room temperature and humidity were within normal range for all procedures; and warming blankets were used for all procedures.
‡MSSA: methicillin-sensitive *Staphylococcus aureus*. Colonization status only available for inpatient surgery. No patients were colonized with methicillin-resistant *Staphylococcus aureus.*

replaced annually. ORs are maintained at 65°F and are humidity controlled. SSIs were evaluated by prospective infection control surveillance according to National Healthcare Safety Network recommendations.

Binary variables were analyzed using the Wilcoxon 2-sample test. Continuous variables were analyzed using univariate linear regression; for ease of presentation, they were also divided into strata to demonstrate changes in mean and range (Table 1). Multivariable regression analysis was not performed because the variables that were significant on univariate analysis (surgery duration, number of door openings, and number of staff) demonstrated collinear coefficients ≥ 0.3. Statistical tests and figures were generated using SAS software (version 9.3; SAS, Cary, North Carolina). The hospital's institutional review board approved this study.

RESULTS

Forty-eight procedures were observed (24 arthroplasty, 7 arthroscopy, 6 podiatry, 5 spine, 4 general surgery, and 2 arthroscopic tendon repair). An average of 54 door openings (range, 21-122) per case were observed, or 0.38 (range, 0.21-0.61) door openings per minute. Door opening times ranged from 6 to 16.5 seconds for manual doors and 18-20 seconds for automatic doors. Settle plates averaged 2.47 CFU (range, 0.00-15), with higher average CFU from plates outside of LAF (3.60 CFU [range, 0.00-15.00]) compared to plates inside of LAF (0.93 CFU [range, 0.00-12.0]) (Fig 1). Increased door openings were statistically associated with higher CFU overall ($P = .03$) and for the subset of cultures outside of LAF ($P = .0012$) but not within LAF ($P = .73$; Table 1). Within LAF, number of staff in the OR was the only variable associated with higher CFU ($P = .03$; Table 1). None of the patients developed an SSI. Multivariable regression analysis was not performed because the variables that were significant on univariate analysis (surgery duration, number of door openings, and number of staff) demonstrated collinear coefficients ≥ 0.3.

DISCUSSION

Increased number of door openings and surgery duration increased CFU counts in the OR, but the relationship between these variables was only observed outside LAF. Within LAF conditions, only the number of staff was associated with higher CFU. The relationship between increased staff and increased CFU within LAF may be due to a larger amount of bacterial shedding from healthcare workers. Researchers also observed temporary displacement of the back instrument table (containing settle plates) outside of LAF when greater numbers of people were involved in the case. This observation may have contributed to the increased CFU seen with high staff numbers and may account for the relationship seen between staff number and CFU in this study but not in other studies that did not use LAF.[11] In addition, the finding that CFU counts increased with door openings is in part accounted for by increased duration. We attempted to adjust for this by looking at CFU as a function of door openings per minute (Table 1). Door openings per minute showed a positive trend in CFU overall and outside LAF but was not statistically significant. These findings suggest that surgery duration contributes to, but does not fully explain, increased CFU counts. Limitations of the study include the possibility of the Hawthorne effect,

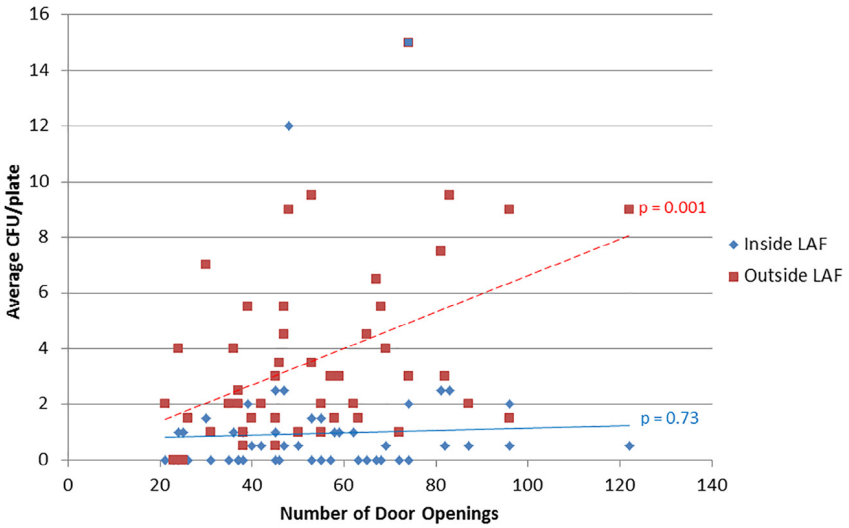

Fig 1. Average Colony Forming Units (CFU) by Door Openings and Laminar Airflow (LAF). Within LAF (diamond; solid line), there is no relationship between door openings and CFU. Outside of LAF (square; dashed line), each door opening increases CFU by 0.07 colonies.

as the procedures being studied were not blinded. The results of this study support the use of LAF and the reduction in number of staff in the OR as effective methods for reducing environmental contamination near the surgical site. In ORs without LAF, reducing door openings may be an effective way to reduce environmental contamination and prevent SSI.

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References

1. Magill SS, Edwards JR, Bamberg W, Beldavs ZG, Dumyati G, Kainer MA, et al. Multistate point-prevalence survey of health care-associated infections. N Engl J Med 2014;370:1198-208.
2. Perl TM, Cullen JJ, Wenzel RP, Zimmerman MB, Pfaller MA, Sheppard D, et al. Intranasal mupirocin to prevent postoperative Staphylococcus aureus infections. N Engl J Med 2002;346:1871-7.
3. Bode LG, Kluytmans JA, Wertheim HF, Bogaers D, Vandenbroucke-Grauls C, Roosendaal R, et al. Preventing surgical-site infections in nasal carriers of Staphylococcus aureus. N Engl J Med 2010;362:9-17.
4. Lutz BD, Jin J, Rinaldi MG, Wickes BL, Huycke MM. Outbreak of invasive Aspergillus infection in surgical patients, associated with a contaminated air-handling system. Clin Infect Dis 2003;37:786-93.
5. Smith EB, Raphael IJ, Maltenfort MG, Honsawek S, Dolan K, Younkins EA. The effect of laminar air flow and door openings on operating room contamination. J Arthroplasty 2013;28:1482-5.
6. Erichsen Andersson A, Petzold M, Bergh I, Karlsson J, Eriksson BI, Nilsson K. Comparison between mixed and laminar airflow systems in operating rooms and the influence of human factors: experiences from a Swedish orthopedic center. Am J Infect Control 2014;42:665-9.
7. Gastmeier P, Breier AC, Brandt C. Influence of laminar airflow on prosthetic joint infections: a systematic review. J Hosp Infect 2012;81:73-8.
8. Pokrywka M, Byers K. Traffic in the operating room: a review of factors influencing air flow and surgical wound contamination. Infect Disord Drug Targets 2013;13:156-61.
9. Andersson AE, Bergh I, Karlsson J, Eriksson BI, Nilsson K. Traffic flow in the operating room: an explorative and descriptive study on air quality during orthopedic trauma implant surgery. Am J Infect Control 2012;40:750-5.
10. Panahi P, Stroh M, Casper DS, Parvizi J, Austin MS. Operating room traffic is a major concern during total joint arthroplasty. Clin Orthop Relat Res 2012;470:2690-4.
11. Mathijssen NM, Hannink G, Sturm PD, Pilot P, Bloem RM, Buma P, et al. The effect of door openings on numbers of colony forming units in the operating room during hip revision surgery. Surg Infect (Larchmt) 2016;17:535-40.